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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,970	11/27/2000	Christopher J R Paszty	A-676A	6512

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/10/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire One month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-124 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-124 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

★ U.S. GPO: 1998-421-832/40208

Part III: Detailed Office Action

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10, 11, 46-50, 61-67, 111 and 112, drawn to nucleic acids, vectors, host cells, expression, and monomeric fusion proteins, classified in class 435, subclass 69.7.

II. Claims 9, 13-17, 40-45, 57, 60, and 107-110, drawn to protein and homodimer thereof, and compositions thereof, classified in class 530, subclass 350.

III. Claim 12, drawn to an assay using transformed cells, classified in class 435, subclass 7.2.

IV. Claims 18-36, 38-39, 70, 71, 73, 74, 78-91, 103, 104, 107 and 108, drawn to antibodies to β10 and hybridoma cells, classified in class 530, subclass 387.9, for example.

V. Claims 37 and 106, drawn to method of treatment using antibodies to homodimeric protein, classified in class 424, subclass 130.1.

VI. Claims 51 and 106, drawn to method of treatment using protein, classified in class 514, subclass 2.

VII. Claims 52 and 113, drawn to a diagnostic assay for protein, classified in class 435, subclass 7.1.

VIII. Claims 53 and 115, drawn to a device comprising a membrane and cells expressing protein, classified in class 435, subclass 382.

IX. Claim 54, drawn to a binding assay using protein, classified in class 435, subclass 7.1.

X. Claims 55 and 116, drawn to gene therapy, classified in class 514, subclass 44.

XI. Claims 56 and 117, drawn to a transgenic animal, classified in class 800, subclass 8.

XII. Claims 58-60, 68, 107, 108 and 118, drawn to heterodimeric protein, classified in class 530, subclass 350.

XIII. Claim 69, drawn to assay for compounds that modulate heterodimer activity, classified in class 435, subclass 7.2.

XIV. Claims 70, 72, 73, 75, 92, 103-105, 107 and 108, drawn to antibodies to β10 heterodimers, classified in class 530, subclass 387.9.

XV. Claim 76, drawn to immunoassay for β10 homodimer, classified in class 436, subclass 501.

XVI. Claims 77, 122 and 124, drawn to immunoassay for heterodimer, classified in class 436, subclass 501.

XVII. Claim 106, drawn to a method of treatment using homodimer, classified in class 514, subclass 2.

XVIII. Claim 106, drawn to a method of treatment using a heterodimer, classified in class 514, subclass 2.

XIX. Claim 106, as drawn to a method of treatment using antibodies to a heterodimer, classified in class 424, subclass 130.1.

XX. Claims 120 and 121, drawn to heterodimeric fusion protein, classified in class 530, subclass 350.

XXI. Claim 123, drawn to a device comprising a membrane and cells expressing heterodimeric protein, classified in class 435, subclass 382.

The inventions are distinct, each from the other because:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons:

The polypeptide of Invention II is related to the nucleic acids of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the

specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention IV because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the antibody of Invention IV because the antibody may be neither made by nor used in the method.

The polypeptide of Invention II is related to the antibody of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The nucleic acids of Invention I are related to the products of Inventions VIII, XI, XII, XX, and XXI because the nucleic acids can be used to manufacture any of the three other products. However, the Inventions are nonetheless distinct, because the nucleic acids can be used for alternative processes, such as in gene therapy or in hybridization assays, and each Invention requires divergent searches. Accordingly, restriction is proper. Similarly, the products of Inventions VIII, XI, XII, XX, and XXI are structurally and functionally distinct products which require divergent searches, and are therefore properly restricted.

The antibodies of Inventions IV and XIV are mutually exclusive groups of structurally and functionally distinct molecules, and therefore require separate search and consideration. Accordingly, restriction is proper.

The products of Inventions I and II are separate and distinct form the antibodies of Invention XIV wherein the products are structurally and functionally distinct, and are not capable of common manufacture or use.

Inventions II and XII are separate and distinct because the proteins have different primary and secondary structures, cannot be made by the same methods, and have different properties and uses.

Invention II is related to Inventions VIII and XI because the latter products may produce the former. However, the inventions are nonetheless unrelated because Invention II may be made by other methods, such as those of Invention I, and because the methods of Inventions VIII and XI may be used other than for the production of the protein. Accordingly, restriction is proper.

Invention II is separate and distinct from each of Inventions XX and XI, wherein the former product is structurally and functionally distinct from the others, and wherein each requires a divergent search.

The remaining pairwise combinations of the products of Inventions IV, VIII, XI, XII, XIV, XX and XXI are separate and distinct, one from the other, because the various products are structurally and functionally distinct, and capable of separate and manufacture and use, and require divergent searches. Accordingly, restriction is proper.

The methods of Inventions I, III, V-VII, IX, X, XIII, and XV-XIX are separate and distinct, each from the others, wherein each has different starting and ending points, involves different method steps, and uses or produces distinct products or results. Accordingly, each requires separate search, and restriction is proper.

The transformed cells of Invention I and Invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells can be used for recombinant production of protein, as claimed in Invention I, or in cellular therapy.

Invention I is distinct from and unrelated to each of Inventions IV-VII, IX, XIII, and XV-

XIX, wherein the products of Invention I are neither made by nor used in the methods of Inventions IV-VII, IX, XIII, and XV-XIX, and wherein each does not require the other. Similarly, the methods of Invention I are distinct from and unrelated to Invention X, wherein the products of Invention I are neither made by nor used in the methods of Invention X, and wherein each does not require the other.

Invention II is distinct from and unrelated to each of Inventions III, V, VII, X, XIII, and XV, XVI, and XVIII-XIX, wherein the products of Invention I are neither made by nor used in the methods of Inventions III, V, VII, X, XIII, and XV, XVI, and XVIII-XIX, and wherein each does not require the other.

Invention II is related to each of Inventions VI, IX, and XVII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used in any of the patentably distinct methods.

Invention IV is distinct from and unrelated to each of Inventions III, VI , IX, X, XIII, and XVI-XIX wherein the products of Invention IV are neither made by nor used in the methods of Inventions III, VI , IX, X, XIII, and XVI-XIX, wherein each does not require the other.

Invention IV is related to each of Inventions V, VII, and XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used in any of the patentably distinct methods.

Inventions VIII, XI and XXI are distinct from and unrelated to each of Inventions III, V-VII, IX, X, XIII, and XV-XIX wherein the products are neither made by nor used in the methods, and wherein each does not require the other.

Invention XII is distinct from and unrelated to each of Inventions III, V-VII, IX, X, XV-XVII and XIX wherein the polypeptide of Invention XII is neither made by nor used in the methods, and wherein each does not require the other.

Invention XII is related to each of Inventions XIII and XVIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used in either of the patentably distinct methods.

Invention XIV is distinct from and unrelated to each of Inventions III, V-VII, IX, X, XV, XVII and XVIII wherein the polypeptide of Invention XIV is neither made by nor used in the methods, and wherein each does not require the other.

Invention XIV is related to each of Inventions XIII and XVI and XIX, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used in either of the patentably distinct methods.

Invention XX is distinct from and unrelated to each of Inventions III, V-VII, IX, X, XIII, and XV-XIV wherein the polypeptide of Invention XX is neither made by nor required for the methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species Requirement:

In addition to the above, in the event that applicants elect Invention IV, a further election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: humanized antibodies, human antibodies, polyclonal antibodies, monoclonal antibodies, chimeric antibodies, CDR grafted proteins, anti-idiotypic antibodies, a variable region fragment, Fab or fragment thereof, or antagonist.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 18-24, 34, 35, 70, 71, 74, 78-79, 89, 90, 92, 93, 103 and 104 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information:

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

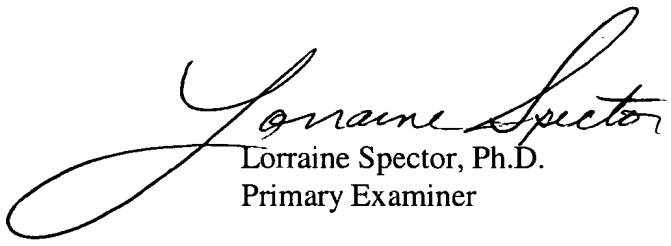
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.



Lorraine Spector, Ph.D.
Primary Examiner

LMS
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6/7/02